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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,505	02/18/2004	Rafail Zubok	532-3X6	2913

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EXAMINER	
CUMBERLEDGE, JERRY L	
ART UNIT	**PAPER NUMBER**
3733	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,505	ZUBOK ET AL.	
	Examiner	Art Unit	
	Jerry Cumberledge	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *19-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2004 and 06 May 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/14/2005 and 06/15/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/382,702, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. There appears to be no support for a drill guide in Application No. 10/382,702. Therefore, the effective filing date of claims 1-18 of the present application is the filing date of Application No. 10/688,632 (10/17/2003), of which the present application is a continuation, and which contains support for a drill guide.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract

on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Election/Restrictions

Applicant's election of Group I (claims 1-18) in the reply filed on 01/22/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 19-24 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected method, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01/22/2007.

Claim Objections

There exists an inconsistency between the language of claim 1 and that of claims 3 and 6 dependent thereon, thus making the scope of the claim unclear. In the preamble of claim 1, line 1, applicant recites "A drill guide" with the insertion plate being only functionally recited, i.e. "...operable to engage an insertion plate...", thus indicating that the claim is directed to the subcombination, "A drill guide". However, in claims 3 and 6, applicant positively recites the insertion plate as part of the invention, i.e. "...the first alignment element of the insertion plate includes an alignment stem..." and "...the second alignment element of the insertion plate includes the alignment stem extending in an anterior direction...", thus indicating that the combination, a drill guide and an insertion plate, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For

examination purposes claims 1-9 will be considered as being drawn to the subcombination, a drill guide.

There exists an inconsistency between the language of claim 1 and that of claims 4 and 8 dependent thereon, thus making the scope of the claim unclear. In the preamble of claim 1, line 1, applicant recites "A drill guide" with the intervertebral replacement device being only functionally recited, i.e. "...operable to engage an insertion plate that maintains first and second members of an intervertebral disc replacement device..." thus indicating that the claim is directed to the subcombination, "A drill guide". However, in claims 4 and 8, applicant positively recites the intervertebral disc replacement device as part of the invention, i.e."...the first member of the intervertebral disc replacement device includes a vertebral contact surface..." and "...the first member of the intervertebral disc replacement device includes a first vertebral contact surface...", thus indicating that the combination, a drill guide and an intervertebral disc replacement device, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claims 1-9 will be considered as being drawn to the subcombination, a drill guide.

There exists an inconsistency between the language of claim 10 and that of claims 12 and 15 dependent thereon, thus making the scope of the claim unclear. In the preamble of claim 10, line 1, applicant recites "A drill guide" with the insertion plate being only functionally recited, i.e. "...operable to engage an insertion plate...", thus indicating that the claim is directed to the subcombination, "A drill guide". However, in claims 12 and 15, applicant positively recites the insertion plate as part of the invention, i.e."...the insertion plate includes an alignment stem... " and "...the second alignment element of the insertion plate includes the alignment stem extending in an anterior direction...", thus indicating that the combination, a drill guide and an insertion plate, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claims 10-18 will be considered as being drawn to the subcombination, a drill guide.

There exists an inconsistency between the language of claim 10 and that of claims 13 and 17 dependent thereon, thus making the scope of the claim unclear. In the preamble of claim 10, line 1, applicant recites "A drill guide" with the intervertebral replacement device being only functionally recited, i.e. "...operable to engage an insertion plate that maintains first and second members of an intervertebral disc replacement device..." thus indicating that the claim is directed to the subcombination, "A drill guide". However, in claims 13 and 17, applicant positively recites the

intervertebral disc replacement device as part of the invention, i.e "...the first member of the intervertebral disc replacement device includes a first vertebral contact surface..." and "...the first member of the intervertebral disc replacement device includes a first vertebral contact surface...", thus indicating that the combination, a drill guide and an intervertebral disc replacement device, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claims 10-18 will be considered as being drawn to the subcombination, a drill guide.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Gill et al. (US Pub. 2003/0187454 A1).

Gill et al. disclose a drill guide, comprising: a shaft (Fig. 13, ref. 74) having a proximal end (Fig. 13, end ref 72) and a distal end (Fig. 13, end near ref. 76); and a guide member (Fig. 13, ref. 76) disposed at the distal end of the shaft and operable to engage an insertion plate that maintains first and second members of an intervertebral disc replacement device in registration with one another for insertion into an intervertebral disc space of a spinal column, wherein the guide member includes at least one guide bore (Fig. 13, ref. 80) operable to align with an area of a vertebral bone

of the intervertebral disc space to which one of the first and second members of the intervertebral disc replacement device is to be attached. The guide member includes a first alignment element (Fig. 13, remarked, below) operable to engage a second alignment element of the insertion plate and to enable a target orientation of a longitudinal axis of the guide bore relative to at least one of the vertebral bone and the one of the first and second members of the intervertebral disc replacement device. The first alignment element of the guide member includes an alignment stem (Fig. 14a, ref. 84). The guide bore is disposed at least partially through the third alignment element (Fig. 13, remarked, below) such that the target orientation of the longitudinal axis of the guide bore is directed through the at least one through hole. The guide member includes a posteriorly directed surface (Fig. 14a, remarked, below) and a spaced apart anterior directed surface (Fig. 14a, remarked, below); the first alignment element of the guide member includes the alignment bore extending from the posteriorly directed surface at least partially through the guide member toward the anteriorly directed surface (Fig. 13, below). The alignment bore has a longitudinal axis that is offset from a longitudinal axis of the shaft (Fig. 13). The guide member includes at least two guide bores (Fig. 13, ref. 82).

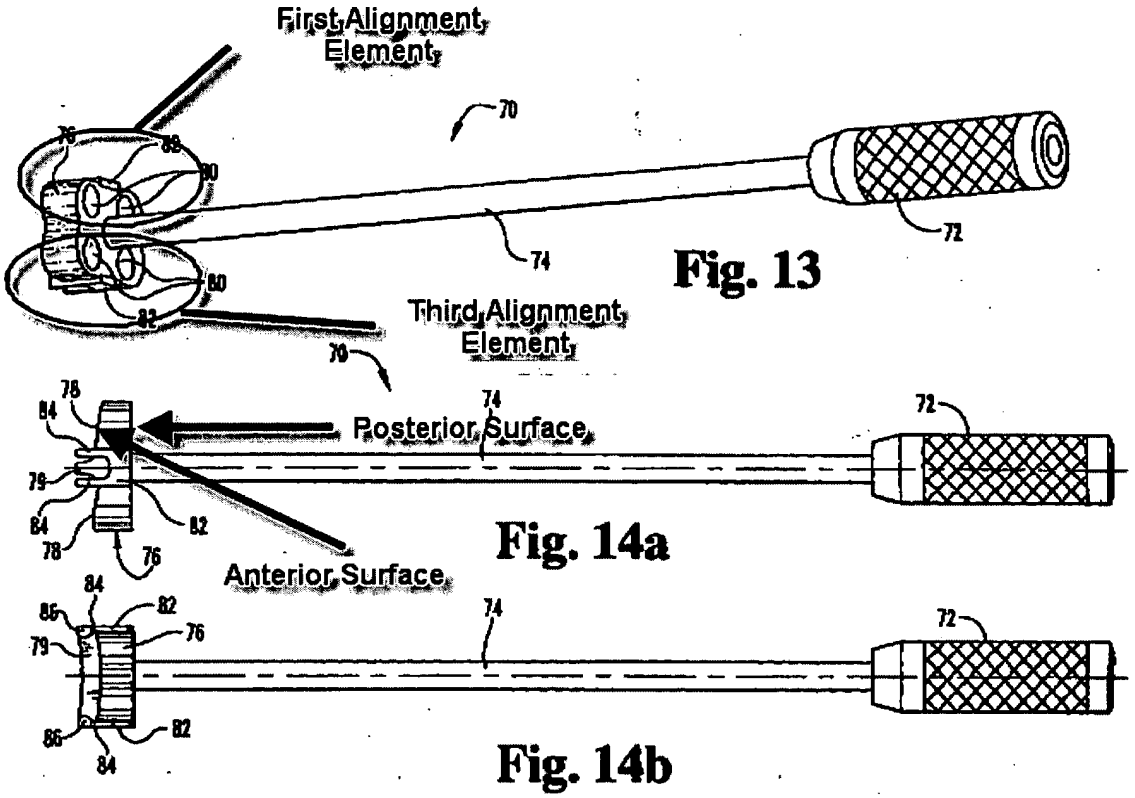
Gill et al. disclose a drill guide, comprising: a shaft (Fig. 13, ref. 74) having a proximal end (Fig. 13, end ref 72) and a distal end (Fig. 13, end near ref. 76); and a guide member (Fig. 13, ref. 76) disposed at the distal end of the shaft and including at least one guide bore (Fig. 13, ref. 80), the guide member being operable to engage an insertion plate that maintains first and second members of an intervertebral disc

replacement device in registration with one another for insertion into an intervertebral disc space of a spinal column, wherein: the guide member is operable to achieve at least first and second alignment modes with respect to the insertion plate, in the first alignment mode, the guide member is operable to engage the insertion plate such that the at least one guide bore aligns with an area of a first vertebral bone of the intervertebral disc space to which one of the first and second members of the intervertebral disc replacement device is to be attached, and in the second alignment mode, the guide member is operable to engage the insertion plate such that the at least one guide bore aligns with an area of a second vertebral bone of the intervertebral disc space to which the other of the and second members of the intervertebral disc replacement device is to be attached. The guide member includes a first alignment element (Fig. 13, remarked, below) operable to variably engage a second alignment element of the insertion plate to achieve the first and second alignment modes; in the first alignment mode, the first alignment element of the guide member is operable to.engage the second alignment element of the insertion plate to enable a first target orientation of a longitudinal axis of the guide bore relative to at least one of the first vertebral bone and the first member of the intervertebral disc replacement device; and in the second alignment mode, the first alignment element of the guide member is operable to engage the second alignment element of the insertion plate to enable a second target orientation of the longitudinal axis of the guide bore relative to at least one of the second vertebral bone and the second member of the intervertebral disc replacement device. One of the first alignment element of the guide member and the

second alignment element of the insertion plate includes an alignment stem (Fig. 14a, ref. 84). The guide member of the drill guide further includes at least a third alignment element (Fig. 13, remarked, below) operable to: (i) engage the at least one through hole of the first flange when the alignment stem is received within the alignment bore in the first alignment mode to further enable the first target orientation of the longitudinal axis of the guide bore, and (ii) engage the at least one through hole of the second flange when the alignment stem is received within the alignment bore in the second alignment mode to further enable the second target orientation of the longitudinal axis of the guide bore. The guide bore is disposed at least partially through the third alignment element (Fig. 13, remarked, below) such that the target orientations of the longitudinal axis of the guide bore may be directed through the respective through holes in the first and second alignment modes. The guide member includes a posteriorly directed surface (Fig. 14a, remarked, below) and a spaced apart anterior directed surface (Fig. 14a, remarked, below); the first alignment element of the guide member includes the alignment bore extending from the posteriorly directed surface at least partially through the guide member toward the anteriorly directed surface (Fig. 13); and the second alignment element of the insertion plate includes the alignment stem extending in an anterior direction for engagement with the alignment bore (Fig. 13). The alignment bore has a longitudinal axis that is offset from a longitudinal axis of the shaft (Fig 13).

With regard the statement of intended use and other functional statements (e.g. "...operable to engage an insertion plate that maintains first and second members of an intervertebral disc replacement device in registration with one another for insertion into

an intervertebral disc space of a spinal column..., ...operable to engage a second alignment element of the insertion plate..., ...the guide member is operable to achieve at least first and second alignment modes with respect to the insertion plate...), they do not impose any structural limitations on the claims distinguishable over the device of Gill et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill et al. (US Pub. 2003/0187454 A1).

With regards to claims 17 and 18, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the drill guide of Gill et al. with a fourth alignment element with two bore holes, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER